K091243 1/1

JUN 26 2009

# 510(K) SUMMARY
# OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC™ Ankle Plating System.

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| Submitted By: | Wright Medical Technology, Inc. |
| Date: | April 16, 2009 |
| Contact Person: | Sarah Holtgrewe |
| | Sr. Regulatory Affairs Specialist |
| Proprietary Name: | **ORTHOLOC™ APS** |
| Common Name: | Bone Plate System |
| Device Classification Regulation: | 21 CFR 888.3030--Class II |
| Device Product Code & Panel: | HRS: Plate, Fixation, Bone/ Orthopedics |

## DEVICE INFORMATION

### A. INTENDED USE

The ORTHOLOC™ Ankle Plating System (APS) is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula.

### B. DEVICE DESCRIPTION

The ORTHOLOC™ APS consists of straight and pre-contoured plates that accept non-locking and locking screws of various lengths and diameters. All components are manufactured from titanium alloy and available sterile or non-sterile.

The design features of the ORTHOLOC™ APS are substantially equivalent to the design features of other devices previously cleared for market.

### C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the ORTHOLOC™ APS are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the ORTHOLOC™ APS is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Wright Medical Technologies, Inc.
% Ms. Sarah Holtgrewe
5677 Airline Road
Arlington, TN 38002

Re: K091243
Trade/Device Name: ORTHOLOC Ankle Plating System (APS)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: April 27, 2009
Received: April 28, 2009

Dear Ms. Holtgrewe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091243

# Indications for Use

510(k) Number (if known):

Device Name: ORTHOLOC® APS

Indications For Use:

The ORTHOLOC® Ankle Plating System (APS) is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K091243